

(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
13 September 2001 (13.09.2001)

PCT

(10) International Publication Number  
WO 01/66038 A2(51) International Patent Classification<sup>7</sup>:

A61F 2/06

(74) Agent: NESS, Anton, P.; P.O. Box 2269, Bloomington, IN 47402-2269 (US).

(21) International Application Number: PCT/US01/06764

(22) International Filing Date: 2 March 2001 (02.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/186,586 3 March 2000 (03.03.2000) US

(71) Applicant: COOK INCORPORATED [US/US]; 925 South Curry Pike, P.O. Box 489, Bloomington, IN 47402-0489 (US).

(72) Inventor: GREENBERG, Roy, K.; 240 Fox Hollow Drive, Suite 211, Mayfield, OH 44124 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

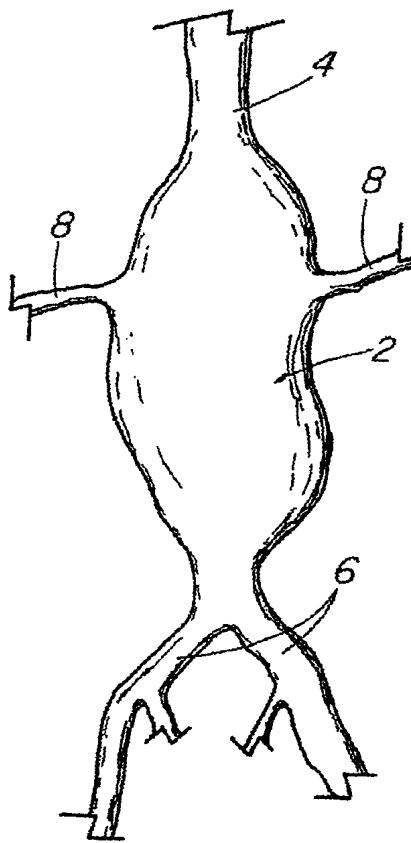
(84) Designated States (regional): Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: ENDOVASCULAR DEVICE HAVING A STENT



**(57) Abstract:** A stent (10, 20, 30, 40, 50, 58, 60, 80, 90, 100, 150, 254, 256, 300) having an inflatable member or a plurality of members affixed directly thereto. One type of inflatable member, or pair or plurality of members, may be affixed to the outer stent surface to expand upon inflation to seal against the vessel wall, and optionally to each other as well, and may be annular (14, 18, 20, 42, 46, 82, 94) or spirally (22, 24, 26, 84) or asymmetrically (32, 34, 36) configured. In another embodiment a member (304), or pair of opposed members (306), can be affixed to the inner stent surface and used to occlude the lumen upon inflation. The device of the present invention can also be utilized with conventional stent grafts (152) to protect branch vessels that are involved in the aneurysm span.

WO 01/66038 A2



*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## ENDOVASCULAR DEVICE HAVING A STENT

DescriptionTechnical Field

This relates to the field of medical devices and more particularly to endovascular devices having a stent.

Background of the Invention

5 In recent years treatment of aneurysms has included the use of stent grafts that are emplaced within the vascular networks, and include one or more stents affixed to graft material. The stent grafts are secured at a treatment site by endovascular insertion utilizing introducers and catheters, whereafter they are enlarged radially and remain in place by self-attachment to the vessel wall. In 10 particular, stent grafts are known for use in treating descending thoracic and abdominal aortic aneurysms where the stent graft at one end defines a single lumen for placement within the aorta and at the other end is bifurcated to define two lumens, for extending into the branch arteries.

15 One example of such a stent graft is PCT Publication No. WO 98/53761 in which the stent graft includes a sleeve or tube of biocompatible graft material (such as Dacron or polytetrafluoroethylene) defining a lumen and several stents secured therealong, with the stent graft spanning the aneurysm extending along the aorta proximally from the two iliac arteries, and the reference also discloses the manner of deploying the stent graft in the patient utilizing an introducer assembly.

20 The graft material-covered portion of the single-lumen proximal end of the stent graft bears against the wall of the aorta above the aneurysm to seal the aneurysm at a location that is distal of the entrances to the renal arteries. Thin wire struts of a proximal stent extension traverse the entrances without occluding them while securing the stent graft in position within the aorta when the stent self-expands, 25 since no graft material is utilized along the proximal stent; an extension is affixed to one of the legs of the stent graft to extend along a respective iliac artery, and

optionally extensions may be affixed to both legs. Another known stent graft is the Zenith AAA stent graft sold by William A. Cook Australia Pty., Brisbane, AU.

5 Stent grafts are also known in which an inflatable balloon is positioned within the collapsed stent graft before and during placement of the stent graft in a patient using an introducer assembly; the balloon is then expanded to increase the diameters of the several stents and the graft material until the stent graft bears against the vessel wall at least at its distal and proximal ends. Such stent grafts are disclosed in U.S. Patent No. 5,639,278; No. 5,562,728 and No. 5,718,724. In U.S. Patent No. 5,330,528, a plurality of expandable chambers is disclosed, with several 10 supply pipes extending to respective chambers for inflation thereof.

15 Use of such stent grafts requires that the graft not close off or occlude or obstruct entrances to other branch arteries, such as the renal arteries. Placement of the single-lumen or proximal end of the stent graft, at least the portion having graft material, must be located spaced axially from branch arteries and toward the aneurysm neck.

It is desired to provide an endovascular device that is useful for aneurysms that span the branch arteries, or that have intrarenal necks of minimal length.

#### Summary of the Invention

20 In accordance with the present invention, an endovascular device includes at least one stent and at least one inflatable portion or member which is affixed to the stent, with the stent generally having no graft material thereon.

25 In one embodiment, the inflatable portion is disposed about a lumen of the device to define a cuff and is utilized either to expand a stent or to define a seal externally to a stent or to a stent graft, and both may be found on a particular device of the present invention. The inflatable portion may be so oriented as to be annular, or may be spiral, or may be asymmetric in its inflated state. If a device includes more than one inflatable portion, each such portion may be inflatable by a dedicated discrete lumen, or a single lumen with multiple branches to the respective inflatable portions.

In another embodiment, the device of the present invention may be used with a stent graft and extend radially outwardly therefrom to enter a branch vessel. In one particular application where the stent graft is to be emplaced for treating an abdominal aortic aneurysm, the device of the present invention would be affixable 5 to the stent graft remote from the iliac legs thereof for placement at a proximal neck of the aneurysm, to enter one of the renal arteries and to define a lumen in communication with the stent graft lumen. The stent of the device would be expanded within the proximal portion of the renal artery. A plurality of such devices could be utilized with the stent graft for maintaining the patency of numerous branch 10 arteries.

In another aspect, the device of the present invention could be utilized to extend from the single-lumen end of a stent graft that otherwise would terminate only just adjacent to a branch artery; the device could be used for aneurysms having proximal necks of minimal length at the renal artery entrances, where conventional 15 stent grafts could not generally be used. The stent of the device would comprise a plurality of spaced struts or legs and would traverse the branch artery entrance without occluding it since no graft material would be utilized on the stent, allowing blood perfusion through openings between the stent struts or legs. An inflatable portion of the device would surround the end portion of the stent graft and be 20 inflatable to become pressed against the vessel wall, thereby sealing the aneurysm.

In a further embodiment, a device of the present invention could comprise an elongate main stent either without graft material or with graft material at both the distal and proximal end portions. Additional stents could extend radially outwardly from the main stent for placement within branch vessels, each with one or more 25 inflatable portions, and each defining a lumen in communication with the lumen of the main stent such as through openings between struts of the main stent.

Another embodiment of the stent/balloon of the present invention could include a plurality of members affixed along the outer stent surface that are spaced apart when deflated providing spacings for instrumentation to extend therebetween

and outwardly from the stent, but which press against each other and the vessel wall to seal about the stent when inflated.

An additional embodiment provides an occlusion device wherein, for example, a pair of opposed inflatable portions are affixed to the inner surface of the 5 stent such that upon inflation they press against each other and traverse the lumen of the stent.

In additional aspects, the device of the present invention could utilize stents with a pattern of spiral struts, or with a series of stent segments. A stent may be utilized that includes struts at one end that are expandable to rotate radially 10 outwardly until in engagement with the wall of the aorta about the periphery of a branch vessel, for securing the placement of the device with respect to the branch artery.

The present invention also includes a method comprising the steps of 15 deploying a stent and an inflatable member at a deployment site within a vessel of a patient, and inflating the inflatable member to abut the vessel wall and define a seal between the stent and the vessel wall.

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings.

#### Brief Description of the Drawings

20 FIGURE 1 is a longitudinal section view of an aneurysm of the aorta adjacent to the iliac arteries and showing the renal arteries;

FIGURES 2 and 3 are isometric views of first and second embodiments of the present invention having a stent and a single annular inflatable band or multiple annular bands;

25 FIGURES 4A and 4B are isometric views of a third embodiment before and after balloon inflation, where the balloons have a nonannular pattern such as spiral;

FIGURE 5 is similar to FIGS. 4A and 4B of a fourth embodiment where the balloons have an asymmetric pattern;

FIGURE 6 is a fifth embodiment of the present invention having a first annular inflatable portion at one end to seal outwardly against the vessel wall, and a second annular inflatable portion proximate the other end that would expand to fill the aneurysm sac;

5 FIGURES 7 and 8 are sixth and seventh embodiments of the present invention having a Z-type stent or a spiral stent, respectively, and multiple branches with stent balloons;

FIGURE 9 is an eighth embodiment having a stent that is adapted to be secured at the entrance to a branch artery;

10 FIGURE 10 is a ninth embodiment illustrating a main stent with two branch stents extending radially outwardly therefrom, each having two annular inflatable portions, with the main stent also having two annular inflatable portions positioned on either side of the pair of branch stents;

15 FIGURE 11 is an isometric view illustrating an embodiment of the present invention *in situ* in the aorta extending from an end of an abdominal aortic stent graft proximally past entrances to opposed renal arteries, and having an inflatable portion sealing against the vessel wall to seal the aneurysm;

20 FIGURES 13 and 14 illustrate the placement of the proximal neck device of FIG. 11, with the device initially placed at a minimal-sized infrarenal neck, and subsequently inflated in FIG. 12 to approximate an extended proximal aneurysm neck to facilitate placement of the abdominal aortic stent graft;

25 FIGURE 14 is an isometric view of the device of the present invention utilized with an elongate stent graft for an aneurysm that extends past the renal arteries, with devices of the present invention extending radially outwardly from the stent graft to enter the branch arteries to maintain the patency thereof, while the elongate stent graft proximal end is secured to the vessel wall above the branch arteries;

30 FIGURE 15 is an isometric view similar to FIG. 14 with the several inflatable portions of a stent graft assembly having respective lumens for separate selective inflation thereof; and

FIGURES 16 to 19 are end views of an additional embodiments of the present invention that comprise occluders.

Detailed Description

In FIG. 1 is illustrated an aneurysm 2 of the aorta 4 in the abdomen of a patient proximal to the iliac arteries 6, with the renal arteries 8 spaced proximally thereof. Stent grafts presently known, such as that disclosed in PCT Publication No. WO 98/53761, could not generally be utilized at least alone to treat such an aneurysm 2 since the wall of the stent graft main lumen formed by graft material would traverse the branch arteries thereby occluding flow, as the proximal end of the stent graft would have to be secured to healthy vessel wall spaced from the aneurysm to thereby seal off the aneurysm proximally, with the legs of the stent graft being secured to the iliac artery walls below the aneurysm, to seal the aneurysm distally.

The endovascular device 10 of the present invention, as shown in FIG. 2, includes at least one stent 12 and at least one inflatable portion 14, with a lumen 16 extending axially therethrough. In most Figures, the stent frame structure is depicted generally as a cylindrical grid having struts that are oriented at an angle with respect to the longitudinal axis of the lumen, and the inflatable portions may be affixed to surfaces of the grid such as by adhesive bonding.

In FIG. 3, device 10 utilizes second and third annular inflatable portions 18, 20 in addition to first inflatable portion 14. With this device, the first and second inflatable portions 14,18 could expand the stent 10, while the third inflatable portion 20 could be a sealing balloon that surrounds the stent and expand to form a seal against the wall of the aorta surrounding the periphery to the entrance to a branch artery (as illustrated in FIG. 11). The several inflatable portions may have separate discrete inflation lumens (see FIG. 13).

The device 20 of FIG. 4A includes several inflatable portions or members or balloons 22,24,26 that extend in spiral fashion about the stent outer surface spaced apart when not inflated, which would allow instrumentation to extend

through and between the struts of the stent and spacings 28 between the deflated members. In FIG. 4B, the members are shown inflated as they would be within a vessel to press against the vessel walls, and would also press against each other to define a seal between the stent and the vessel wall.

5 In FIG. 5, several inflatable members or balloons 32,34,36 of device 30 are shown in an asymmetric pattern selected to complement certain vasculatory anatomy such that spaces are defined between the balloons when they are deflated but which can seal against the vessel wall and each other after inflation except in the larger spacings 38 between balloons that may align with branch vessel entrances  
10 to permit blood flow thereinto.

Device 40 of FIG. 6 includes a first inflatable portion 42 at a first end of stent graft 44, to establish a seal against healthy vessel wall adjacent the entrance to an aneurysm. A second inflatable portion 46 is larger, preferably thin-walled, for filling the aneurysm sac upon inflation thereof.

15 In FIG. 7 is illustrated another embodiment 50 of the endovascular device of the present invention. A main stent 52 includes a first end 54 and a second end 56. Second and third stents 58,60 are added in a modular fashion prior to inflation of any balloons or after selective inflations, to extend radially outwardly from main stent 52 remote from ends 54,56 to extend into and along branch arteries. Main  
20 stent 52 includes at least two inflatable portions 62 as shown, and each of second and third stents 58,60 is shown to include one or more inflatable portions 64. Graft material 66 is shown surrounding portions of main stent 52 adjacent to first and second ends 54,56; use of graft material 66 is optional, however, and may be combined with balloons. Lumens 68,70 of second and third stents 58,60 are in communication with central lumen 72 of main stent 52. Second and third stents 58,60 would extend outwardly from main stent 52 through openings between the struts thereof. Second and third stents 58,60 would provide a mechanism to preserve flow into branch vessels through the use of external balloons to seal the vessels off from the aneurysmal sac.

FIGS. 8 to 10 illustrate types of stents useful with the present invention. In FIG. 8, stent 80 illustrates both an annular member 82 at one end, and another portion of the stent that is shown to be completely or partially affixed with members 84 in a pattern identical to the struts 86 of the stent. Stent 90 of FIG. 9 has spiral struts 92 and an associated member 94 oriented to expand against the outer diameter; this may add flexibility and improved sealing to the system.

In FIG. 10, stent 100 is a button stent that has a greater expansile capacity at proximal end 102 with strut portions 104 that are expandable to deflect radially outwardly and rotate backwardly to become engaged with the vessel wall or with struts of another stent 106 surrounding the periphery of the entrance of a branch artery 108 to prevent movement of the stent into the branch artery 108; the inflatable portion 110 seals the branch artery from the aneurysm in which stent 106 is affixed to provide a sealing mechanism so that a stent assembly may be defined for multiple "branches". Strut portions 104 preferably are of the type to self expand upon release from within a retractable sheath (not shown) but may be balloon expandable and shapable by altering the balloon shape and expansion/inflation characteristics.

FIGS. 11 to 13 depict placement of an endovascular device of the present invention *in situ* within an abdominal aortic aneurysm. In FIG. 11, a device 150 of the present invention is used in conjunction with an abdominal aortic stent graft 152 of conventional design, for use in treating an aneurysm 154 having an infrarenal neck 156 of minimal length adjacent to branch or renal arteries 158,160. Device 150 includes a stent 162 initially positioned (FIG. 12) to traverse the entrances 164,166 of renal arteries 158,160, with the stent being free of graft material and thereby not occluding the renal arteries. Device 150 may be of the type that is self-expandable, or is expandable by use of a stent-expanding balloon. Annular inflatable portion 168 of device 150 surrounds stent 162 and is located immediately adjacent to entrances 164,166 of renal arteries 158,160 and is shown inflated (FIG. 12) to seal against vessel wall to close off the entrance 156 to the aneurysm 154. When device 150 is so placed and inflatable portion 168 has been inflated, device 150

approximates an aneurysmal neck of substantial length enabling the use of a conventional stent graft. The proximal end of the stent graft 152 is insertable into the lumen of device 150 and attachable thereto following the same procedures as if it were being attached to the vessel wall. Optionally, the device may be affixed 5 about a distal end of the stent graft prior to placement, to simplify the procedure.

In FIG. 14, an elongate stent graft 200 extends from legs 202,204 to a proximal end 206, and positioned in and along aneurysm 208 from iliac arteries 210,212 to healthy vessel wall 214 adjacent to entrance 216. Aneurysm 208 is of 10 the type to encompass the entrances to branch arteries, such as renal arteries or superior mesenteric arteries (SMA), which of course can not be allowed to become occluded or blocked by the stent graft.

FIG. 15 demonstrates potential pre-deployment access or inflation lumens 250 for the inflatable sealing members 252 each of the branch segments 254 of a stent graft assembly 256.

15 The present invention also is useful in defining a detachable occluder 300. As seen in FIGS. 16 and 17, the inflatable member is mounted along the inside of the stent 302 and is uninflated when the stent is being placed; the member may be annular 304, or may comprise opposing portions 306,306. Then, as shown in FIGS. 18 and 19, the inflatable portion(s) is (are) expanded by a diffusible solution, not 20 only to fully expand the stent but also to completely traverse the lumen 308 of the stent and thereby completely occlude the artery. The inflatable portion(s) may be the length of the stent, and may be from 10 to 40 mm in length. After inflation, the inflation mechanism may be detached.

25 One stent useful with the present invention is the Z-STENT™, sold by Cook Incorporated of Bloomington, Indiana. A similar stent is disclosed in U.S. Patent No. 4,580,568. Another stent is disclosed in U.S. Patent No. 5,015,253 and having a spiral strut configuration.

30 A stent useful with the present invention could comprise stainless steel, Nitinol, titanium alloy, tantalum or Elgiloy, among others. The stents could be lined with thin-walled material that is possibly biodegradable or dissolvable to prevent

balloon intrusion into the lumen of the stent. The balloons defining the inflatable portions could comprise latex, silicone rubber, PET (polyethylene terephthalate) or nylon and so forth, and could be impermeable or semipermeable. Attachment of the inflatable member to the stent may be by use of an appropriate adhesive or bonding agent. The luminal inflation mechanism could be a single lumen connected to each inflatable portion, or a plurality of discrete lumens that are separately inflatable for selective and/or sequential inflation thereof. The filling mechanism can involve a series of detachable lumens that are detached by a trigger mechanism at the delivery device level, a sheath that is advanced over the balloon lumen to separate the devices, or a pressure type valve. In addition, the lumens of the balloons can be joined, in which case all the balloons can be filled off a single lumen, or there can be discrete filling chambers with separate lumens, involving separate disconnect mechanisms.

The substance used to inflate the lumen can vary from standard saline or air, to a silicone based substance or something that will solidify over time. The mechanism of this can occur by coupling a balloon material that is selectively permeable with an inflation medium that solidifies with the diffusion of the substance to which the balloon material is permeable. This would allow the chemical constitution of the balloon contacts to vary, thus altering the physical properties over time.

Another approach would be to provide a substance within the deflated member or balloon, that expands when exposed to ultraviolet or visible light that activates a catalyst within the substance, whereby the substance foams up to inflate the inflatable member; in such a case no inflation lumen is necessary, and the light energy can be transmitted by an optical fiber within the catheter such as being secured to the wire guide.

An inflation lumen monitoring device (such as a wire or module that measures pressure) can be placed within, or just outside a balloon lumen such that when the balloon is inflated the device can register the pressure transmitted to the balloon lumen or the wall of the aneurysm/artery. The sensor will have to have a

- 11 -

means of transmitting the data to a monitor placed on the patient in the proximity of the device or over the phone line. -- as some pacemakers do.

The inflated member can either be big and bulky to fill the aneurysmal sac or, more likely, have properties to be sandwiched between stents, in such a way so 5 that it becomes a "lining" like graft material over the lumen or outer stent scaffold upon inflation.

Additionally, an inflatable member may be utilized within the stent lumen and sufficiently affixed thereto along the inner surface when the stent is in its reduced dimension state, to be utilized for expansion of the stent upon deployment 10 within a vessel whereafter the inflatable member may thereafter be deflated and removed.

15

20

25

30

Claims

1. Medical apparatus comprising:

at least one stent (10,20,30,40,50,58,60,80,90,100,150,254,256)  
having a lumen therethrough and being compressible to a relatively small dimension  
5 for placement into a delivery device for delivery to a deployment site in a vessel of  
a patient and for expansion, to a relatively large dimension, and at least one  
inflatable member (14,18,20,22,24,26,32,34,  
36,42,46,82,84,94) secured to said one stent and having means for inflating the  
member, said at least one inflatable member being sufficiently small in deflated state  
10 to be capable of placement into said delivery device for delivery to said deployment  
site, said at least one inflatable member being disposed in a location on said one  
stent so that when the member is inflated, it will provide a seal between the said  
one stent and the wall of the vessel at the deployment site.

2. Medical apparatus for placement in a collapsed condition in a delivery  
device for delivery to a deployment site in a vessel of a patient, said apparatus  
comprising at least one stent (10,20,30,40,50,58,60,80,90,  
100,150,254,256,300) and at least one member or expandable member  
(14,18,20,22,24,26,32,34,36,42,46,82,84,94,304,306), characterized in that the  
said one member is secured to the stent, is expandable in an outward direction to  
engage the vessel and to act or remain as a graft to provide a seal between the  
vessel and the interior of the stent, or is expandable in an inward direction to close  
off the stent lumen.

2. Intravascular medical apparatus for treating a patient with an aortic  
aneurysm extending across a region embracing the renal arteries, said apparatus  
comprising at least one stent (10,20,30,40,50,58,60,80,90, 100,150,254,256),  
when deployed, serving to extend from upstream of the said region to a position  
downstream of the renal arteries, characterized in that the said one inflatable  
member (14,18,20,22,24,26, 32,34,36,42,46,82,84,94) is secured to the stent and  
is expandable in an outward direction from the stent to provide a seal between the  
vessel in the region of the downstream position and the interior of the stent.

4. Apparatus according to claim 2 or 3, wherein certain parts of the said one stent are free of graft material whereby body fluid may pass through said certain parts to other vessels or said arteries.
5. Apparatus according to claim 2, 3 or 4, wherein said at least one member (14,18,20,22,24,26,32,34,36,42,46,82,84,94) is expandable between the vessel wall and the outer surface of the stent.
6. Apparatus according to claim 5, wherein said at least one member (14,18,20,42,46,82,94) when expanded is disposed circumferentially around said stent, or wherein said at least one member includes a plurality of expandable members attached to said outer surface at respective locations, or one or more members (14,18,20,42,82,94) are disposed circumferentially around said one stent and spaced apart axially along the length of said one stent.
7. Apparatus according to claim 6, wherein said one or more members (22,24,26,84) are disposed in respective spiral configurations for example in parallel, and spaced apart from each other, or wherein said members are spaced sufficiently closely to press against each other upon inflation.
8. Apparatus according to claim 6 or 7, wherein another medical device extends radially outwardly through said one stent and between selected adjacent ones of said members such that said members press against said another medical device or against each other or both, upon inflation.
9. Apparatus according to claim 1, wherein a member (304) is affixed to an inner surface of said stent (300) to expand radially inwardly upon inflation, or wherein a plurality of said members (306) are affixed to the stent along an inner surface thereof to expand radially inwardly upon inflation, or wherein at least two said members (306) are positioned to face each other within said lumen and to press against each other upon inflation to occlude said lumen.
10. Apparatus according to claim 1, wherein said stent (90) includes at least one spiral strut (92) and said at least one inflation member (94) is affixed to at least one circumference of said spiral strut, or wherein said stent includes a plurality of

spiral struts with several of said spiral struts having respective said inflation members affixed thereto.

11. Apparatus according to claim 1, 2 or 3, wherein said stent further includes graft material affixed thereto.

12. Apparatus according to claim 1, 2 or 3, wherein said stent includes a large inflatable member (46) affixed to the stent along an outer surface thereof to substantially fill an aneurismal sac (2) upon inflation.

13. Apparatus according to claim 11 or 12, wherein said inflation member (14,18,20,22,24,26,42,82,84,94) is affixed to an outer surface of said stent and is annular to define a seal with a wall of said vessel upon inflation.

14. Apparatus according to claim 1, 2 or 3, wherein at least a second stent (254) extends outwardly from an outer surface of said stent (256) to an end that is within a branch vessel upon deployment, said stent includes a pair of annular ones of said inflatable members affixed to said outer surface of said stent on distal and proximal sides of said second stent to seal said stent against said vessel wall distally and proximally of said branch vessel.

15. Apparatus according to claim 14, wherein said second stent (254) includes at least one inflatable member affixed thereto proximate said end of said second stent, and/or wherein a third stent extends outwardly from said outer surface of said stent between said pair annular ones of said inflatable members, to a respective end that is within another branch vessel upon deployment.

16. Apparatus according to claim 1, 2 or 3, wherein in plurality of said inflatable members (32,34,36) are arranged in an asymmetric pattern selected to complement vasculatory anatomy and to define at least one space between said plurality of inflatable members upon their inflation to permit blood flow through said at least one space.

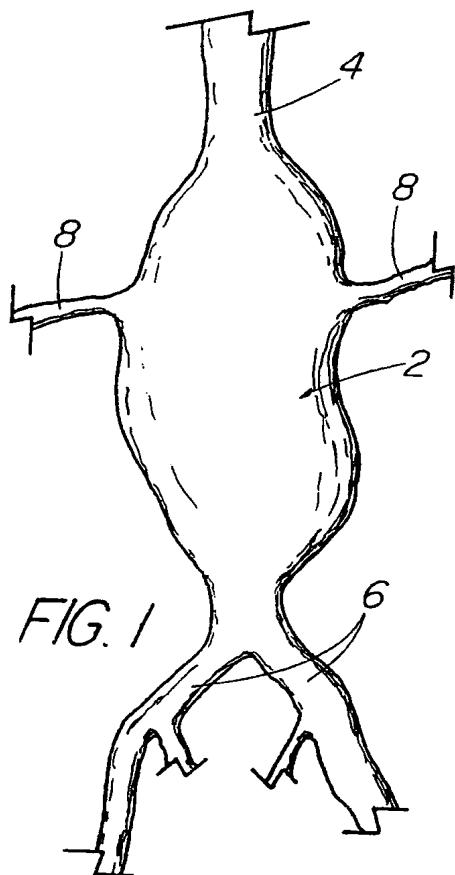


FIG. 1

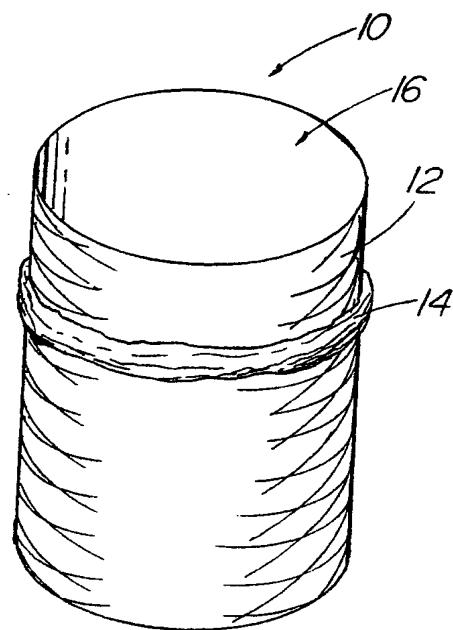


FIG. 2

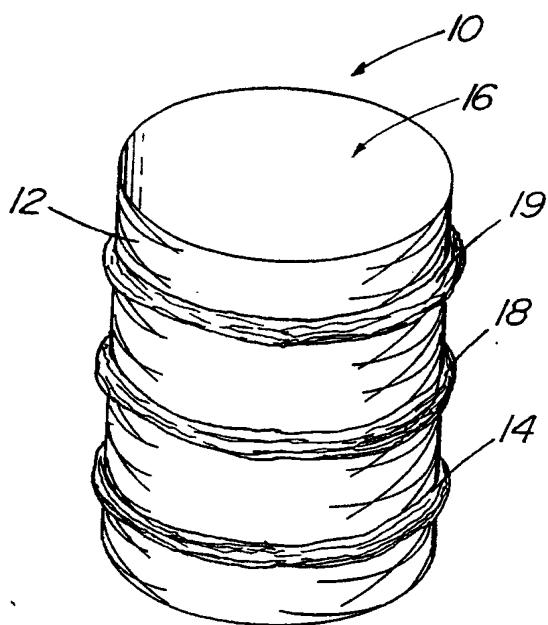


FIG. 3

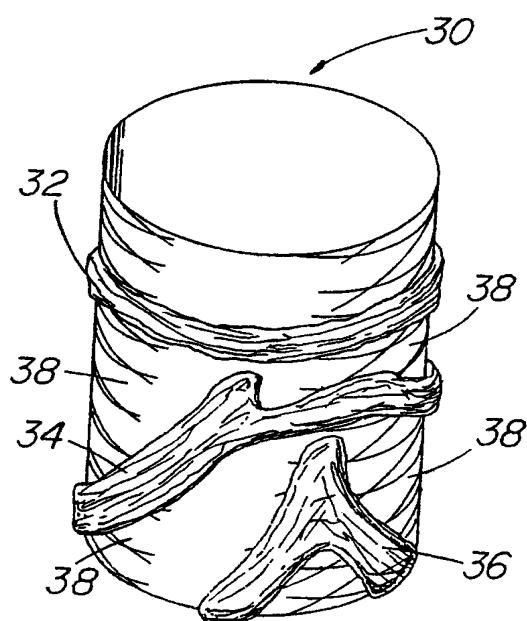


FIG. 5

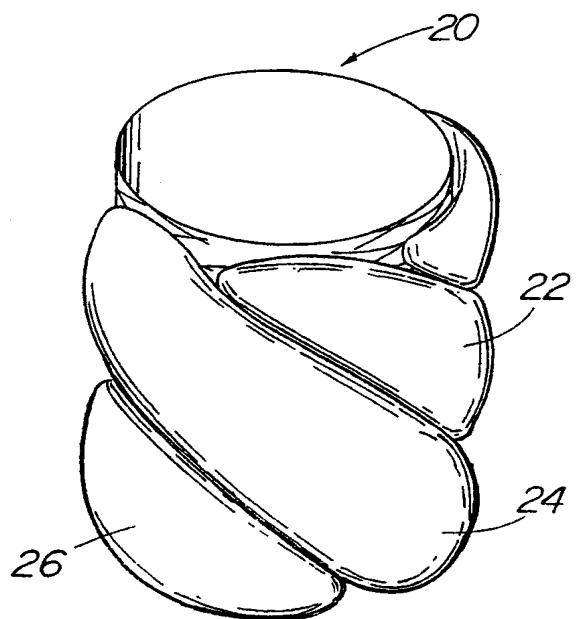


FIG. 4B

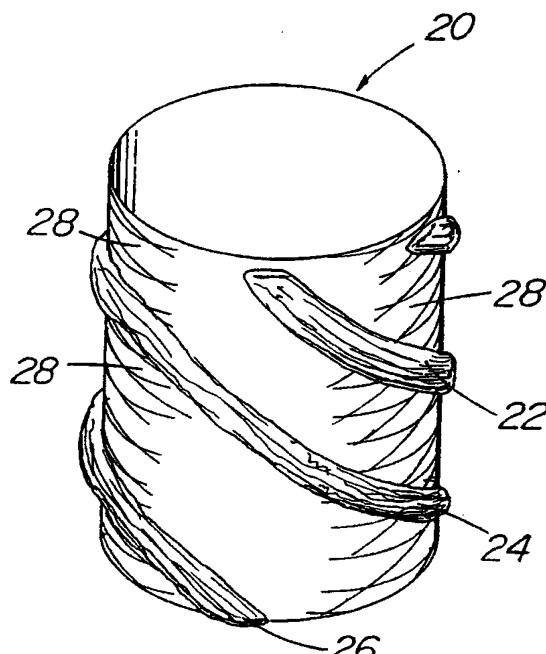


FIG. 4A

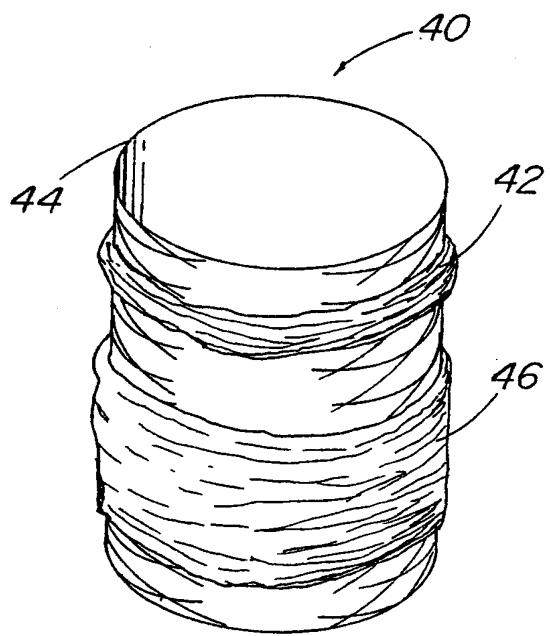


FIG. 6

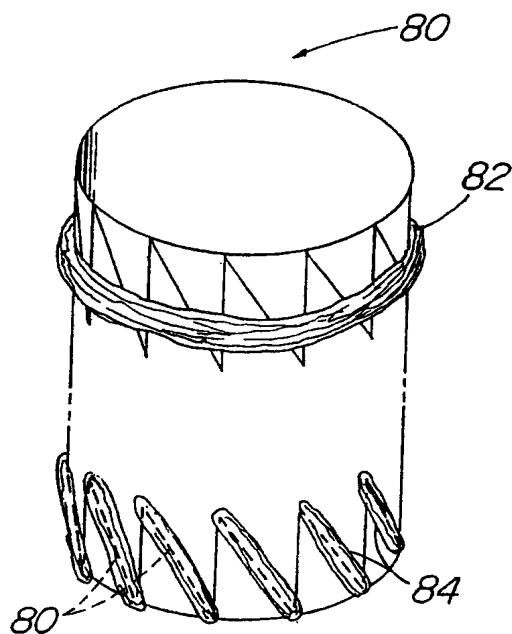
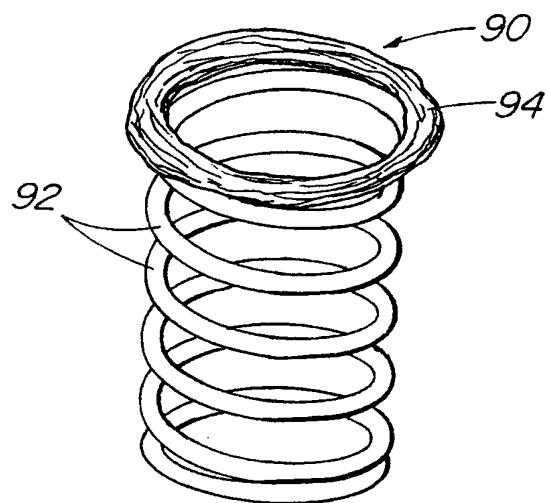
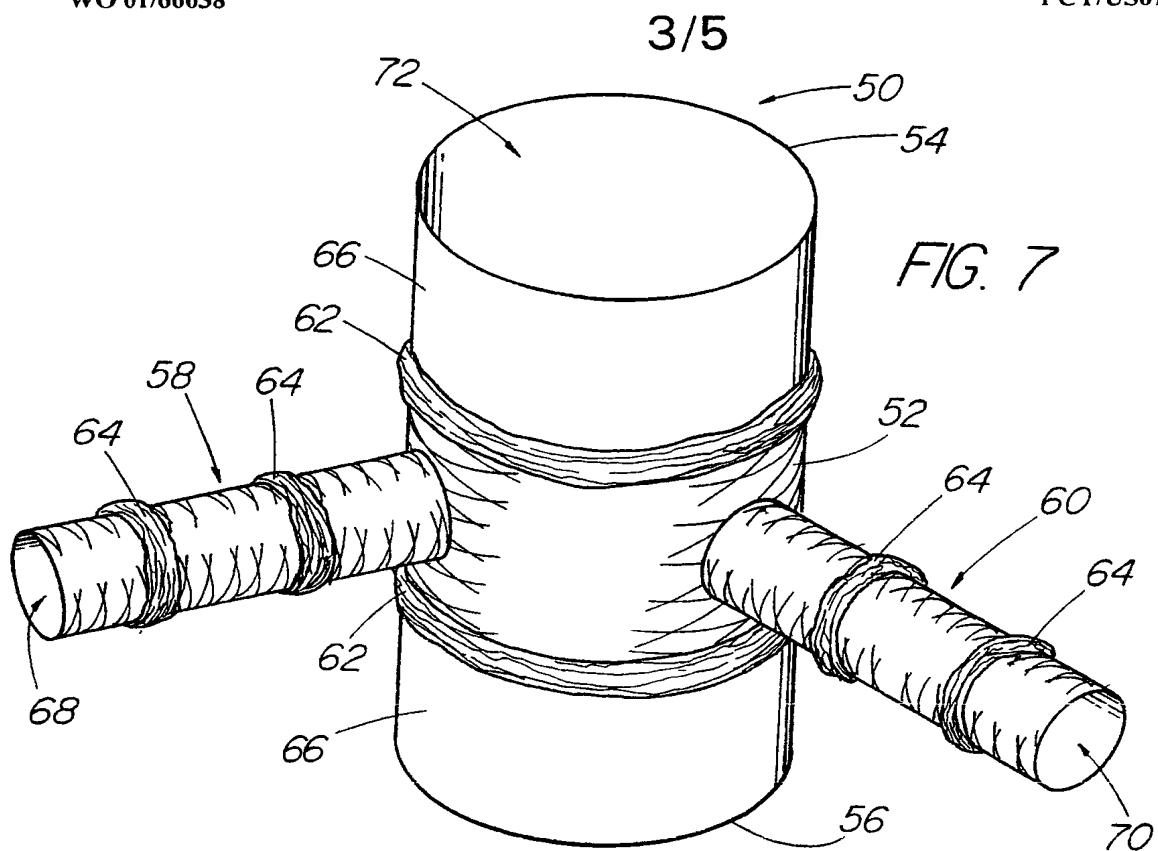


FIG. 8



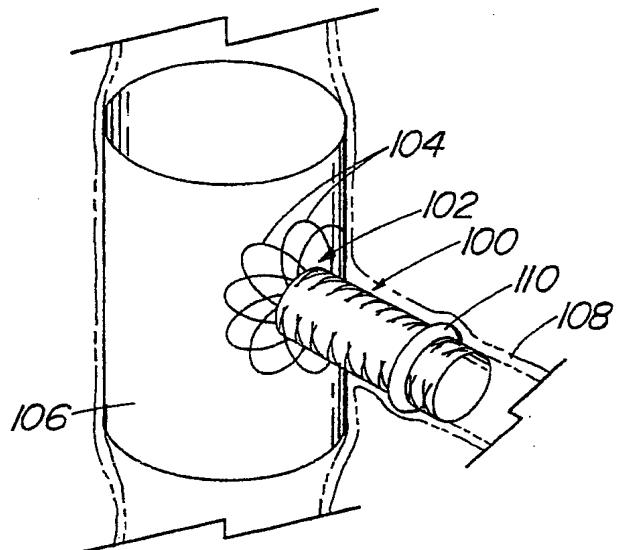


FIG. 10

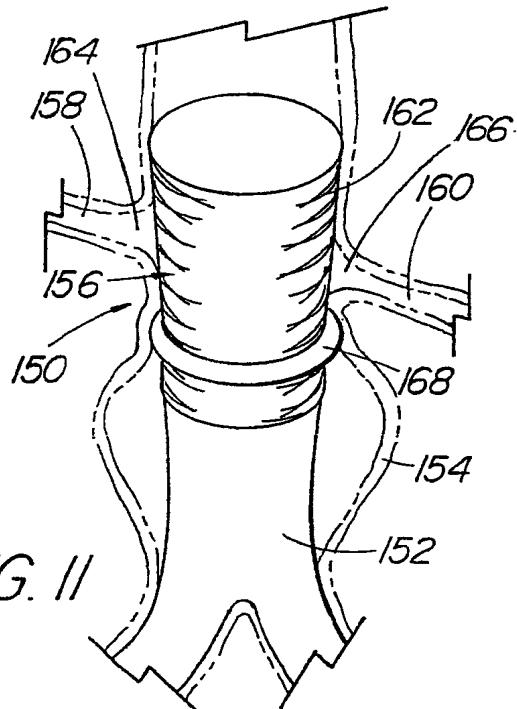


FIG. 11

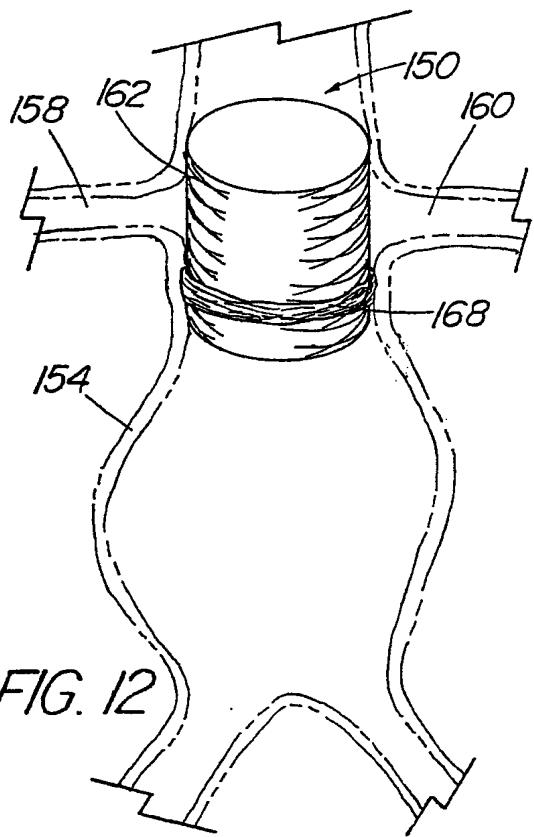


FIG. 12

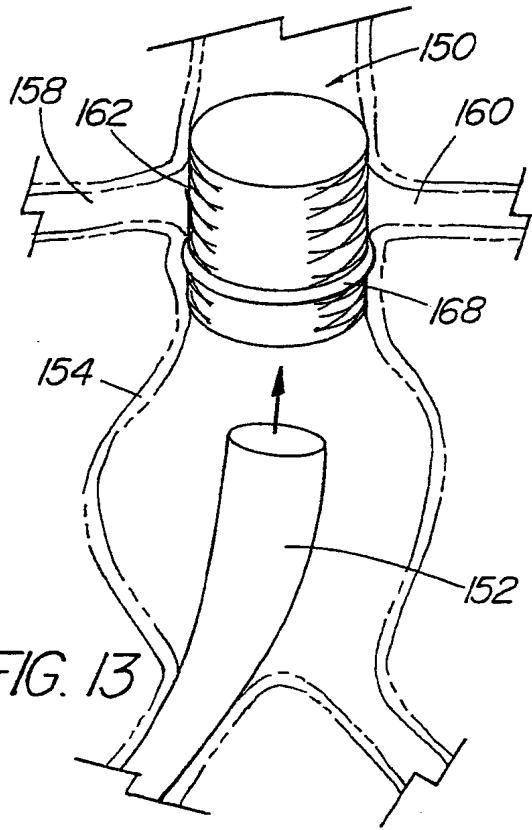
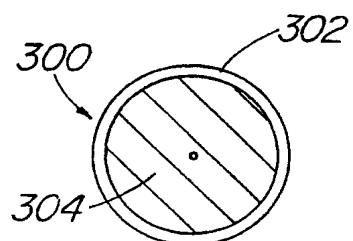
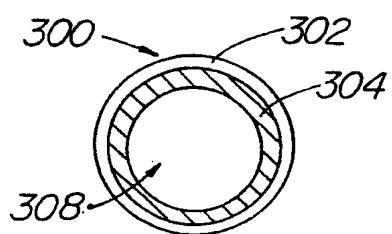
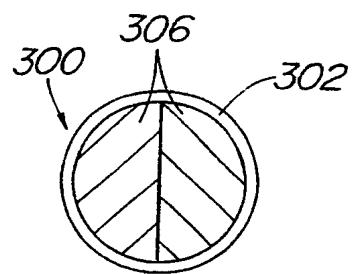
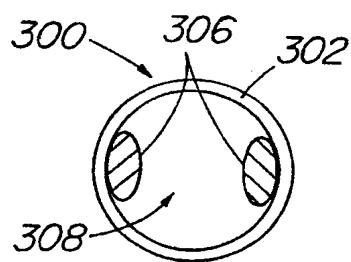
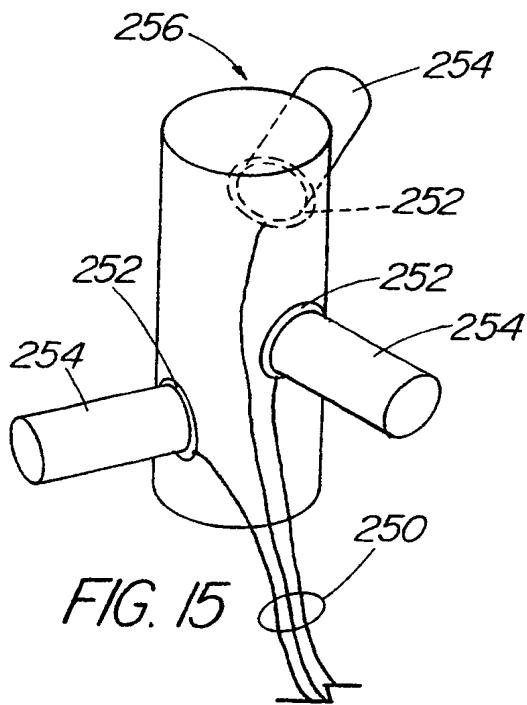
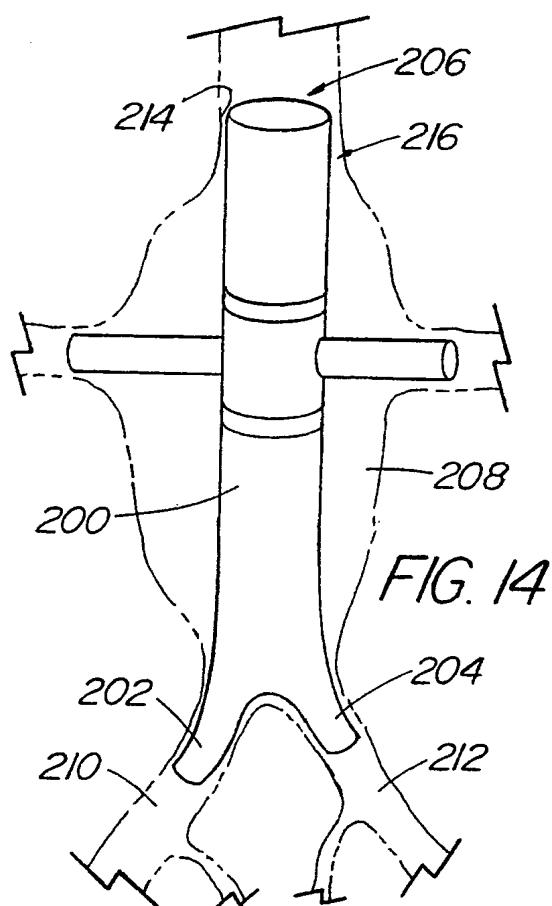


FIG. 13



# INTERNATIONAL SEARCH REPORT

Int'l Application No  
PCT/DE 01/00402

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/16

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 955 904 A (ATEBARA NEAL ET AL) 11 September 1990 (1990-09-11) figures 7-10 column 5, line 63 -column 6, line 51 column 8, line 33 - line 49	1
A	---	2-11
X	US 5 662 706 A (LEGERTON JEROME A ET AL) 2 September 1997 (1997-09-02) figure 1 column 2, line 37 -column 3, line 20 column 5, line 39 -column 8, line 12	1
A	---	1-11
	FR 2 696 340 A (BRITO MUGUERZA MARIA CARMELINA) 8 April 1994 (1994-04-08) page 4, line 26 -page 5, line 18 figure 2 page 2, line 1 - line 6	
	---	
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*&\* document member of the same patent family

Date of the actual completion of the international search

1 June 2001

Date of mailing of the international search report

12/06/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl.  
Fax: (+31-70) 340-3016

Authorized officer

Mary, C

# INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/DE 01/00402

**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 39 26 536 A (ADATOMED PHARMA & MED) 14 February 1991 (1991-02-14) claims 1-13 column 2, line 11 - line 63 ----	1-11
A	RU 2 106 832 C (BAGROV SERGEJ NIKOLAEVICH; FEDOROV SVJATOSLAV NIKOLAEVICH; NOVIKOV SERG) 20 March 1998 (1998-03-20) abstract ----	1
P,A	WO 00 67677 A (OUSLEY PAULA J ; TERRY MARK A (US)) 16 November 2000 (2000-11-16) figures 7,8 page 7, line 10 -page 8, line 9 -----	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/DE 01/00402

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4955904	A	11-09-1990	NONE		
US 5662706	A	02-09-1997	AU	3079497 A	07-01-1998
			WO	9748005 A	18-12-1997
FR 2696340	A	08-04-1994	ES	1022501 U	01-04-1993
DE 3926536	A	14-02-1991	NONE		
RU 2106832	C	20-03-1998	NONE		
WO 0067677	A	16-11-2000	AU	4833100 A	21-11-2000

# INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/DE 01/00402

## A. KLASIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 7 A61F2/16

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

## B. RECHERCHIERTE GEBIETE

Recherchierte Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole )  
IPK 7 A61F

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

EPO-Internal, WPI Data, PAJ

## C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 4 955 904 A (ATEBARA NEAL ET AL) 11. September 1990 (1990-09-11) Abbildungen 7-10 Spalte 5, Zeile 63 -Spalte 6, Zeile 51 Spalte 8, Zeile 33 - Zeile 49	1
A	---	2-11
X	US 5 662 706 A (LEGERTON JEROME A ET AL) 2. September 1997 (1997-09-02) Abbildung 1 Spalte 2, Zeile 37 -Spalte 3, Zeile 20 Spalte 5, Zeile 39 -Spalte 8, Zeile 12	1
A	FR 2 696 340 A (BRITO MUGUERZA MARIA CARMELINA) 8. April 1994 (1994-04-08) Seite 4, Zeile 26 -Seite 5, Zeile 18 Abbildung 2 Seite 2, Zeile 1 - Zeile 6	1-11
	---	
	-/-	



Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen



Siehe Anhang Patentfamilie

- Sonderart Kategorien von angegebenen Veröffentlichungen :
- \*A\* Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
- \*E\* älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
- \*L\* Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
- \*C\* Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Aussistung oder andere Maßnahmen bezieht
- \*P\* Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
- \*T\* Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
- \*X\* Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erforderlicher Tätigkeit beruhend betrachtet werden
- \*Y\* Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erforderlicher Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
- \*&\* Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
1. Juni 2001	12/06/2001
Name und Postanschrift der Internationalen Recherchenbehörde Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Bevollmächtigter Bediensteter  Mary, C

# INTERNATIONALER RECHERCHENBERICHT

Int. nationales Aktenzeichen

PCT/DE 01/00402

## C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
A	DE 39 26 536 A (ADATOMED PHARMA & MED) 14. Februar 1991 (1991-02-14) Ansprüche 1-13 Spalte 2, Zeile 11 - Zeile 63 ----	1-11
A	RU 2 106 832 C (BAGROV SERGEJ NIKOLAEVICH; FEDOROV SVJATOSLAV NIKOLAEVICH; NOVIKOV SERG) 20. März 1998 (1998-03-20) Zusammenfassung ----	1
P, A	WO 00 67677 A (OUSLEY PAULA J ; TERRY MARK A (US)) 16. November 2000 (2000-11-16) Abbildungen 7,8 Seite 7, Zeile 10 -Seite 8, Zeile 9 -----	

# INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen  
PCT/DE 01/00402

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie			Datum der Veröffentlichung
US 4955904	A 11-09-1990	KEINE			
US 5662706	A 02-09-1997	AU 3079497 A	WO 9748005 A		07-01-1998 18-12-1997
FR 2696340	A 08-04-1994	ES 1022501 U			01-04-1993
DE 3926536	A 14-02-1991	KEINE			
RU 2106832	C 20-03-1998	KEINE			
WO 0067677	A 16-11-2000	AU 4833100 A			21-11-2000

